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Fulbright & Jaworski
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Minneapolis, MN 55402-2112

EXAMINER

MATTER, KRISTEN CLARETTE

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3771

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06/20/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/537,854	Applicant(s) FISHER ET AL.	
	Examiner KRISTEN C. MATTER	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-10 and 13-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-10 and 13-23 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Action is in response to the amendment filed on 4/28/2008. Claims 1 and 13-21 have been amended, claims 22 and 23 have been added, and no claims have been cancelled. Currently, claims 1-4, 7-10, and 13-23 are pending in the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 3, 13, 14, 15, 16, 17, 18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shayan (US 6,772,756) in view of Frank (US 4,903,850).

Regarding claims 1, 13, 18, and 20, Shayan discloses a vaporizing device with a reservoir (40, 22) and a removable vapor-concentrating lid (12) with an opening (11) for the inhalation of a volatile substance (column 2, lines 50-55). Examiner contends that volatile is synonymous with effervescent. Shayan does not disclose that the vapor-concentrating lid comprises a central depressed area for loosely engaging a user's nasal area. However, Frank discloses a vaporizing device for inhalation of vapors by a user with a lid (14) having a centrally depressed area (see figures 1 and 2) and a plurality of vents (147) (see column 8, lines 1-15). The lid is adapted to concentrate a vapor from the reservoir (i.e., as opposed to letting the vapor disperse randomly into the ambient air). In addition, some of the vapor would be emitted into the ambient air through the vents (147) (see column 8, lines 10-15). Depending on how hard the user presses his

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or her face into the area, the nasal area would be loosely engaged. In addition, as seen in Figure 1, the nasal area (i.e., the nostrils) is loosely engaged even if the bridge of the nose is sealed. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Shayan's device with a removable hood as taught by Frank for allowing the user to better direct the vapor into the nose for inhalation. Furthermore, although Frank does not explicitly disclose that the vents are smaller in area than the opening of the reservoir, examiner contends that is an obvious design consideration to one of ordinary skill in the art to size the vents (147) such that they would be smaller than the opening of the reservoir, since such a modification would have involved a mere change in the size of a component inasmuch as the vents still allowed ambient air and exhaled air to flow in and out of the hood. See also *In re Rose*, 105 USPQ 237 (CCPA 1955).

Regarding claim 2, the reservoir disclosed by Shayan can be considered a cup (see Figure 3).

Regarding claim 3, Shayan discloses that the device can be made of a plastic (column 4, lines 59-60) and that the receptacle and top can be made integrally (column 6, lines 50-55). However, to the extent that to the extent that Shayan is silent as to the material of the reservoir specifically, it is considered an obvious design choice to use a material suitable for a given use. See also *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960), in which the selection of a known material based on its suitability for its intended use supported a prima facie case of obviousness.

Regarding claims 14-17, the modified device disclosed by Shayan and Frank has all of the structural limitations needed to perform the recited method steps and is fully capable of doing

so. It would have been obvious to one of ordinary skill in the art at the time the invention was made, upon seeing the modified device, to perform the recited method steps of the instant claim. Depending on the type of pharmaceutical substance added to the reservoir, any number of different conditions could be treated. Furthermore, the use of hot water as a carrier (or to be vaporized) would generate steam (i.e., humidified air).

Claims 1-3, 7, 8, 13, and 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen (US 6,868,694) in view of Fuisz et al. (US 6,062,213).

Regarding claims 1, 13, and 18-23, Nielsen discloses a system comprising a reservoir (22) comprising an opening (top of reservoir), a removable lid (12) comprising a central depressed area (area inside of cup) of a size and shape whereby during use a user's nasal area could be loosely engaged by the central area and wherein the lid further comprises a plurality of vents (14) centrally located in the depressed area of the lid that are smaller than the opening of the reservoir (see Figure 1). The bottom (18) of the lid would concentrate vapor from the reservoir and emit vapor through the vents (14). The system is fully capable of being used as a portable inhaler and therefore reads on the claimed invention. To the extent that Nielsen is silent as to an effervescent composition to allow a substance to be inhaled (although Nielsen discloses carbon dioxide vapor from the dry ice and effervescent beverages rising through the container), Fuisz et al. is cited as disclosing effervescent compositions immersed in water, for example, to allow a user to inhale an active substance (see column 3, lines 30-45). It would have been obvious to one of ordinary skill in the art at the time of the invention to replace the dry ice in the beverage vessel disclosed by Nielsen with an effervescent composition as taught by Fuisz et al.

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because it would have allowed a user to effectively inhale the therapeutic vapor without inserting anything directly in the nostril, thereby providing more comfort.

Regarding claim 2, as seen in figure 1, the reservoir (22) is a cup.

Regarding claim 3, Nielsen discloses that the cup can be made from acrylic (column 2, line 21), for example, which is selected from the claimed group.

Regarding claim 7, Nielsen discloses the lid and the reservoir are essentially one piece (after being threaded together) and an embodiment with a closable opening (614) in the lid (see figure 6) in which the effervescent composition and water could be added to the reservoir (column 3, lines 4-10).

Regarding claim 8, Fuisz et al. discloses sodium bicarbonate and citric acid as effervescent compositions. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used sodium bicarbonate or citric acid in water as taught by Fuisz et al. in the device of Nielsen because it would have allowed a user to treat certain diseases such as cancer by inhalation therapy without having to insert anything into the nose or mouth.

Regarding claims 14-17, the modified device disclosed by Nielsen and Fuisz et al. has all of the structural limitations needed to perform the recited method steps and is fully capable of doing so. It would have been obvious to one of ordinary skill in the art at the time the invention was made, upon seeing the modified device, to perform the recited method steps of the instant claim, including inhaling an effervescent composition immersed in hot water as taught by Fuisz et al. to generate humidified air. Any number of conditions (such as colds and allergies) could be treated depending on the composition added to the reservoir, which is considered an obvious design choice to one of ordinary skill in the art. For extrinsic evidence please see Krauser (US

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4,523,589) that discloses it is well known that citric acid can be used to treat cold sufferers, for example (column 9, lines 35-40 and column 10, lines 48-50).

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen and Fuisz et al. as applied to claim 1 above, and further in view of Silten (US 2,033,489). The modified Nielsen reference is silent as to the effervescent composition including menthol, eucalyptus oil, flavor additives, excipients, or coloring agents. Silten discloses a device for the inhalation of vapors comprising substances with excipients (column 6, lines 55-60) and dyes (column 1, lines 40-45). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used substances including excipients and dyes as taught by Silten in the modified device of Nielsen in order treat various respiratory diseases by inhalation therapy or to allow a user to see the liquid being vaporized.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shayan and Frank as applied to claim 1 above, and further in view of Ninkov (US 2003/0225003). Shayan is silent as to the specifics of the volatile substance, although Shayan does disclose that the volatile substance can be emulsions or liquids (column 6, lines 40-45). Ninkov discloses useful therapeutic compositions for oral inhalation to treat infection that include liquids and emulsions of polyethylene glycol (paragraphs 0095 and 0137). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a polyethylene glycol emulsion in the modified device disclosed by Shayan and Frank in order to treat a given infection.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shayan and Frank as applied to claim 1 above, and further in view of Silten. Shayan is silent as to the specifics of the volatile substance. Silten discloses a device for the inhalation of vapors comprising substances with excipients (column 6, lines 55-60) and dyes (column 1, lines 40-45). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used substances including excipients and dyes as taught by Silten in the modified device of Shayan and Frank in order treat various respiratory diseases or to allow a user to see the liquid being vaporized.

Allowable Subject Matter

Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's understanding of the rejection of claims 1-3, 13-18, and 20 over Shayan in view of Frank et al. is correct. The rejection of claim 7 over Shayan and Frank et al. was previously withdrawn. Examiner apologizes for any confusion.

Applicant's arguments filed 4/28/2008 have been fully considered but they are not persuasive.

In response to applicant's arguments that the combination of Shayan and Frank et al. would render the Shayan device unsatisfactory for its intended purpose because of Shayan's temperature controlling system, examiner respectfully disagrees and points to column 6, lines 55-60, in which Shayan discloses that the device can be used for aromatherapy (and therefore still inhaled by a user), for example, and the vapor can be allowed to fill a room as opposed to a user just directly inhaling from the opening (11). Therefore, allowing the vapor to cool before a user inhales through a larger lid (as would be done in the combination of Shayan and Frank et al.) would not destroy the reference.

Applicant's arguments on pages 11 and 12 with respect to the size of the vents of Frank et al. are somewhat confusing. It appears that the applicant is calling the top opening of the lid of Frank et al. the "vent." However, in the Action, the vents of Frank et al. are considered the vents 147 located on the sides of the lid (see figure 1). Therefore, reducing the size of these vents to be smaller than an opening of the reservoir would have been an obvious design consideration so long as the vents (147) were still able to allow ambient air into the lid and to exhaust exhaled air/vapor.

In response to applicant's arguments that the bottom of the lid of Nielsen does not concentrate the vapor, examiner respectfully disagrees and contends that the bottom (18) of the lid (12) of Nielsen would concentrate vapor in the same manner as the instant invention. Vapor generated from the reservoir (22) would be concentrated by the fact that the lid has a bottom covering the top of the reservoir and the vapor would then need to find the vents (14) in order to escape.

In response to applicant's arguments that the vent of Nielsen would be the open rim as opposed to the vents (14) because carbon dioxide bubbles would only pass through the vents, examiner points out that depending on the amount of liquid in the reservoir vapor would in fact be concentrated and pass through the vents of Nielsen (i.e., as long as any of the dry ice/effervescent composition was touching the liquid, some vaporization would occur, even if the liquid level was not above the top of the reservoir).

In response to applicant's argument that Silten does not disclose an effervescent composition including excipients/coloring agents, examiner points out that Silten was cited merely to show that excipients and coloring agents are well known and commonly used for inhalation therapy. In addition, specific effervescent compositions including excipients/coloring agents as well known and commonly used components are cited with this Action.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Yeh et al. and Gusman et al. are cited to show that excipients and coloring agents are well known components in effervescent compositions.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen C. Matter whose telephone number is (571) 272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771

/Kristen C. Matter/
Examiner, Art Unit 3771

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